**XLTEK**

# 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR § 807.92.

**Name:** Cameron Mahon
Director of R & D

**Address:** Excel Tech Ltd.
2568 Bristol Circle
Oakville, Ontario
Canada, L6H 5S1

**Telephone:** (905) 829-5300

**Fax:** (905) 829-5304

**Common Names:** Electroencephalograph
Analyzer, Spectrum, Electroencephalogram signal

**Classification Name:** Electroencephalograph
Analyzer, Spectrum, Electroencephalogram signal

**Predicate Devices:** Excel NeuroWorks [FDA(510k) K980214].

**Description:** The Real Patient Excel NeuroWorks is a medical device that transmits EEG information via a wired or wireless communication system to relevant authorities. The Real patient Excel NeuroWorks can use TCP/IP, Intranet, Internet, and physical means to distribute the signal information obtained. The receiving computer will store and archive the signal information. The EEG data stream is captured by a headbox and distributed synchronized with video, audio or screen information in real time.

Real Patient Excel NeuroWorks acquires EEG data and distributes it synchronized with video, audio or screen information in real time to medical personnel in order that they may communicate directly with the patient and technicians without the necessity of being physically on-site. The EEG data stream is captures by a headbox and distributed synchronized with video, audio or screen information in real time.

**Substantial Equivalence:** The Real Patient Excel NeuroWorks is substantially equivalent in safety and effectiveness to the Excel NeuroWorks [FDA(510k) K980214].

**Indications for Use:** The Real Patient Excel NeuroWorks is an electroencephalograph, which is designed to display the electrical signals of the brain.

APR - 9 2001

Ms. Sonja Markez
Regulatory Manager
Excel Tech, Ltd.
2568 Bristol Circle
Oakville, Ontario
Canada L6H 5S1

Re:   K010086
      Trade Name: Real Patient Excel NeuroWorks
      Regulatory Class: II
      Product Code: GWQ
      Dated: January 9, 2001
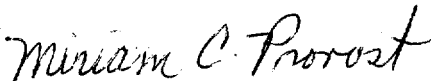      Received: January 11, 2001

Dear Ms. Markez:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

*Miriam C. Prorost*

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
 and Neurological Devices
Office of Device Evaluation
Center for Devices and
 Radiological Health

Enclosure

**XLTEK**
*510(k) Notification for a New Device: Real Patient Excel Neuroworks*
*Statement of Indications for Use*

# Statement of Indications for Use

510(k) Number (if known):          K010086

Device Name:          Real Patient Excel NeuroWorks

Indications for Use:          The Real Patient Excel NeuroWorks is an electroencephalograph which is designed to display the electrical signals of the brain.

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**(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)**

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __✓__          OR          Over-The Counter Use _____
(Per 21§ CFR 801.109)

(Optional Format 1-2-96)

*Miriam C. Provost*
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number __K010086__